

TM -TOLNAFTATE- tolnaftate 1% liquid
Singular Dreamer, Ltd dba True Marker

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredients

Tolnaftate 1%

Purpose

Topical Antifungal

Uses

- Proven clinically effective in the treatment of most fungal infections including related/associated to tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm)
- For effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, discomfort associated to fungal infections
- Prevents most tinea pedis (athlete's foot) with daily use.

Warnings

- **For external use only**
- **Do Not Use** – On children under 2 years of age unless directed by a doctor.
- **When using this product**, avoid contact with eyes.
- **Stop use and ask a doctor**, if irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor (within 2 weeks for jock itch)
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.
- **If pregnant or breast-feeding**, ask a health professional before use.

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor
- Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily
- Supervise children in the use of this product
- For athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily
- For athlete's foot and ringworm, use daily for 4 weeks
- If condition persists longer, consult a doctor

- This product is not effective on the scalp or nails.

Other information

Protect the product in this container from excessive heat and direct sun.

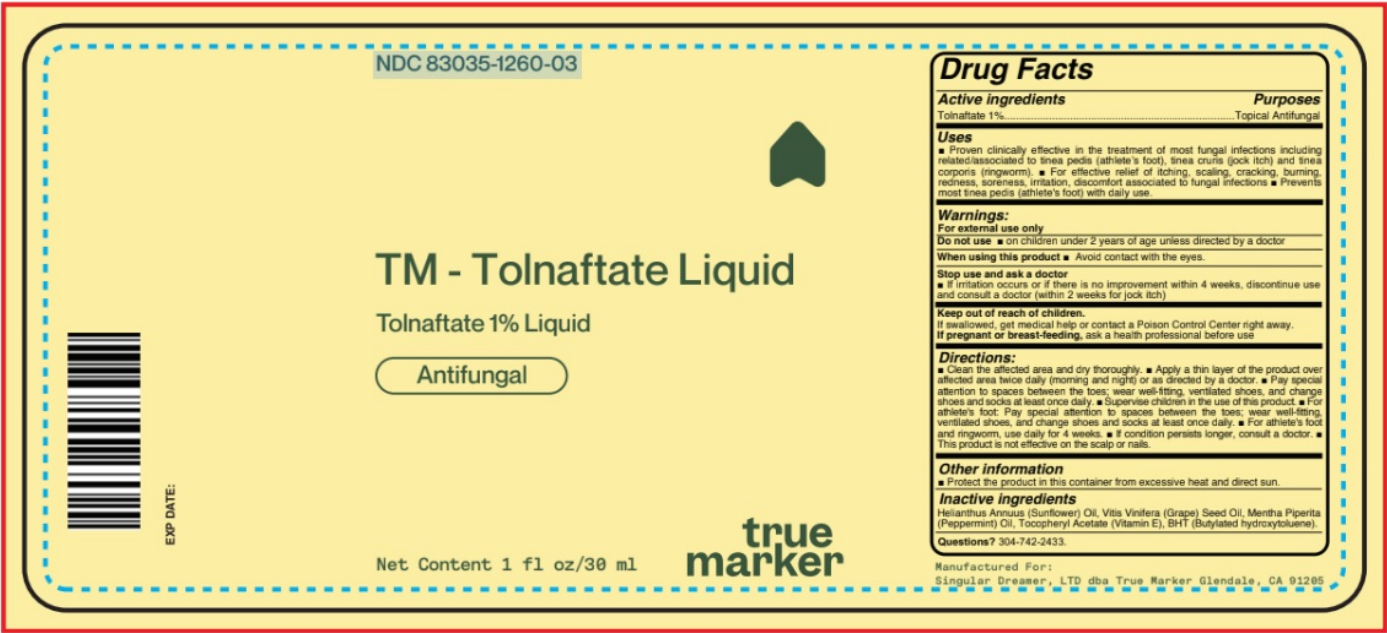
Inactive ingredients

Helianthus Annuus (Sunflower) Oil, Vitis Vinifera (Grape) Seed Oil, Mentha Piperita (Peppermint) Oil, Tocopheryl Acetate (Vitamin E), BHT (Butylated hydroxytoluene)

Questions?

304-742-2433

Product label



TM -TOLNAFTATE

tolnaftate 1% liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83035-1260
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)		TOLNAFTATE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
VITIS VINIFERA FRUIT OIL (UNII: YQ5Q4Y2Z8U)	
PEPPERMINT (UNII: V95R5KMY2B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83035-1260-3	1 in 1 CARTON	03/28/2023	
1		30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/28/2023	

Labeler - Singular Dreamer, Ltd dba True Marker (129504103)**Registrant** - Singular Dreamer, Ltd dba True Marker (129504103)

Revised: 4/2023

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